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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,391

04/14/2004

Joan D. Leonard

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KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

09/26/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@kenyon.com

Office Action Summary

Application No.

10/825,391

Applicant(s)

LEONARD ET AL.

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/30/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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FINAL ACTION

1. This Office action is responsive to Applicant's remarks filed April 30, 2007.

Claims 1-25 have been canceled. Claims 26-36 are under examination. The Examiner acknowledges the Information Disclosure Statement filed April 30, 2007. However, the Examiner has already considered these references on May 18, 2005.

Rejection Maintained

2. The rejection under 35 U.S.C. 102(e) is maintained for claims 26-36 for the reasons set forth on pages 3-5, paragraph 5 of the previous Office action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

As stated in paragraph 4 of this action, Applicant has not perfected the priority data. Therefore, the following art rejection is applied.

Claims 26-36 are rejected under 35 U.S.C. 102(e) as anticipated by Hymas et al (*U.S. Patent No. 6,548,069 B2, issued April 15, 2003*).

Claims 26-36 are drawn to a vaccine composition comprising (a) an immunologically effective amount (i) at least two inactivated *Mycoplasma bovis* biotypes and (ii) an inactivated *Mycoplasma alkalescens*, wherein said immunologically effective amount is protective in a vaccine against Bovine Respiratory Disease resulting from *Mycoplasma* infection, (b) an adjuvant and (c) a pharmaceutically effective carrier.

Hymas et al teach compositions comprising at least two virulent *Mycoplasma bovis* isolates of differing biotypes and an isolate of *M. alkalescens* (column 3). Hymas et al teach that the compositions of the invention may include other antigens (columns

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5-6). Hymas et al teach that the compositions can contain suitable vehicles and adjuvants (columns 10-11). Claims limitations such as, isolating DNA from biotypes, amplifying the DNA by PCR fingerprinting, ribosomal RNA or DNA polymorphisms, separating the amplified DNA by gel electrophoresis and comparing the resulting patterns are being viewed as process limitations. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

Since the Office does not have the facilities for examining and comparing applicant's vaccine with the vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Hymas et al (*U.S. Patent No. 6,548,069 B2, published April 15, 2003*) is not prior art. Applicant urges that they are entitled to a prior date of November 8, 2000 based on U.S. Application Serial No. 09/708,352. It should be noted that Applicant filed a petition on August 21, 2007 to the Petition Office to enter priority information in the specification.

Examiner's Response to Applicant's Arguments

Based on the petition decision made by the Petitions Office and mailed September 6, 2007, Applicant's arguments filed April 30, 2007 have been fully considered but they are not persuasive. The Petitions Office has dismissed Applicant's petition to enter priority information into the specification. Thus, this application is granted the priority benefit to divisional application 10/726,029 filed December 2, 2003. Therefore, Hymas et al (*U.S. Patent No. 6,548,069 B2, issued April 15, 2003*) has a filing date of February 3, 2001 and is made available as art under 35 U.S.C. 102(e).

In view of all of the above, this rejection is maintained.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Status of Claims

4. No claims are allowed.

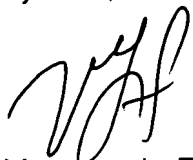
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Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Vanessa L. Ford
Biotechnology Patent
September 12, 2007



NITA MINKIFIELD
PRIMARY EXAMINER
9-14-07